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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.              | CONFIRMATION NO. |
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| 10/767,293  | 01/29/2004  | P. Mark Powell       | VTN-5039-USA-NP                  | 4992             |
| 27777   | 7590        | 12/24/2008           |                                  |                  |
| PHILIP S. JOHNSON<br>JOHNSON & JOHNSON<br>ONE JOHNSON & JOHNSON PLAZA<br>NEW BRUNSWICK, NJ 08933-7003 |             |                      | EXAMINER<br>WIECZOREK, MICHAEL P |                  |
|   |             |                      | ART UNIT                         | PAPER NUMBER     |
|   |             |                      | 1792                             |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/767,293

**Applicant(s)**

POWELL ET AL.

**Examiner**

Michael Wiczorek

**Art Unit**

1792

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/ISD)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date 1/29/2004

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of Group I, claims 1-9 and 21, in the reply filed on August 24, 2008 is acknowledged. Claims 10 through 20 have been cancelled.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 1 recites the limitation "said printing device" in eighth line of the claim. There is insufficient antecedent basis for this limitation in the claim. In the sixth line of claim 1 there is the limitation "introducing a printing comprising..." For the purposes of this examination this limitation was taken to mean "introducing a printing *device* comprising..." Clarification of this issue is requested. Since claim 1 has been rejected as being indefinite, dependent claims 2 through 9 are also rejected as being indefinite.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 1-4, 6-9 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al (U.S. Patent # 6,039,899) in view of Misciagno et al (U.S. Patent # 5,637,265).

Martin et al teaches an automated method and apparatus for manufacturing contact lenses in an inert atmosphere (Abstract).

The apparatus of Martin et al comprise an inert atmosphere chamber in the form of a housing means 24 which is pressurized with nitrogen and comprises at least one isolation shutter in the form of air lock means which allow for entry and egress from the housing means. Furthermore, lens molds in the form of pallets are contained within the housing means during lens manufacturing. (Column 13 Lines 6-12 and Figure 2)

Thus, Martin et al teaches an inert atmosphere chamber that comprises at least one contact lens mold in the form of pallets and at least one isolation shutter in the form of an air lock means and that an overpressure of inert gas in the form of nitrogen is maintained within the chamber.

Since the air lock means allow entry and exit from the chamber, during the manufacturing of the contact lenses this isolation shutters open and close.

Though Martin et al teaches that the housing means 24 comprises a printing device in the form of a pad stamping device (Column 25 Lines 39-67 and Column 26 Lines 1-32), thus a printing device was introduced into the chamber, Martin et al does not teach that this printing device comprises colorant.

Misciagno et al teaches that it is well known in the art to use pad printing to apply patterns to a contact lens mold (Column 1 Lines 21-30) and that applying patterns to the molds involves applying colorant to the molds (Column 4 Lines 24-41). Misciagno et al further teaches that pad printing is conducted using a printing device in the form of a transfer-pad or tampon (Column 1 Lines 53-60).

Martin et al teaches the importance of minimizing the exposure of lens molds to oxygen and Martin et al further teaches that this is achieved by keeping the mold lens in a low oxygen atmosphere during the manufacturing of contact lenses (Column 3 Lines 62-67 and Column 9 Lines 8-24).

Thus, at the time the present invention was made it would have been obvious to one of ordinary skill in the art to introduce a printing device comprising colorant into a chamber with an over pressure of an inert gas. Since applying colorant to a lens mold with a printing device is a known step in the manufacturing of contact lenses and there is a desire within the art to minimize the exposure of contact lens molds to oxygen during contact lens manufacturing, it would have been obvious to one of ordinary skill to introduce the pad printing device comprising colorant of Misciagno et al into the housing means 24 of Martin et al and thus use the printing device to apply colorant to the contact lens mold.

As for removing the printing device from the chamber, Misciagno et al teaches that over the work life of the tampon, which is the printing device, the tampon will fail (Column 2 Lines 24-40) and the defective tampon will have to be replaced (Column 3 Lines 48-54). Thus the act of replacing the defective tampon or printing device would require removing the printing device from the chamber.

As for claims 2 through 4, neither Martin et al or Misciagno et al teach that the chamber comprises less than about 0.5 wt% oxygen prior to opening the shutter, that the chamber comprises less than about 3 wt% oxygen while the shutter is open, nor that the chamber comprises 0.5 wt% oxygen 2 seconds after closing of the shutter. Martin et al does teach, as was discussed within the claim 1 rejection, that the chamber comprises a low oxygen environment (Column 3 Lines 62-67) as well of the negative affects of oxygen on the lens molds (Column 9 Lines 8-24).

It is well settled that determination of optimum values of cause effective variables such as process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Thus since the oxygen level or the weight percentage of oxygen in the chamber is a recognized cause effective variable, it would have been obvious to one of ordinary skill in the art to determine an optimum low level of oxygen within the chamber that is to be maintained throughout the lens manufacturing operation, which includes when the shutter is opened and closed.

As for claim 6, though Martin et al teaches an isolation shutter in the form of an air lock means that opens and closes to allow for entry of the molds into the chamber or housing means

but it does not teach that the shutter remains open for less than about 2 seconds. Martin et al does teach that the longer the molds are exposed to oxygen within the atmosphere the longer it will take to degas the molds of oxygen (Column 2 Lines 13-21). Since the air lock means of Martin et al allows for entry of the molds into the oxygen less housing means 24 it would be obvious to one of ordinary skill in the art that the quicker the air lock means opens and closes to allow entry of the molds into the housing the less time the molds will be exposed to oxygen.

Thus at the time the present invention was made it would have been obvious to one of ordinary skill in the art to have the shutter or air lock means remain open for less than about 2 seconds. Since the air lock means allow for entry of the molds into the housing 24 the quicker the air lock opens and closes, thus the shorter amount of time the air lock means stays open, means less time for the molds to be exposed to oxygen within the atmosphere. Thus it would have been obvious to one of ordinary skill in the art to have the shutter or air lock means of Martin et al remain open for less than about 2 seconds in order to decrease the amount of exposure the molds have with oxygen within the atmosphere.

As for claim 7, as was discussed in the claim 1 rejection the inert gas comprises nitrogen.

As for claim 8, Though Martin et al teaches an overpressure within the chamber it does not teach that this over pressure of inert gas gives rise to an inert gas velocity of at least about 0.5 meter per second measured at an opening in the form of an opened shutter. Martin et al does teach that the overpressure within the chamber should be enough to effectively exclude atmosphere from the system during operation (Column 11 Lines 42-50). Thus Martin et al teaches maintaining the system in an optimal overpressure which would inherently provide an optimal inert gas velocity for inert gas that escapes the system when the shutter or air lock means

opens. As was discussed in the claim 2 through 4 rejections it would be obvious to one of ordinary skill in the art to determine an optimal overpressure for the system, which would inherently provide an optimal escape velocity for inter gas leaving the system when a shutter is opened. Thus it would have been obvious to one of ordinary skill in the art to maintain an optimal overpressure that would give rise to an inert gas velocity of at least about 0.5 meters per second measured at the opening of an open shutter or air lock means.

As for claim 9, as was discussed in the claim 1 rejection the colorant is applied by pad stamping in the form of pad printing the colorant to the contact lens mold.

In the case of claim 21, since it is a broader version of claim 1 it is rejected for the same reasons as were presented in the claim 1 rejection.

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al in view of Misciagno et al as applied to claim 1 above, and further in view of Critchley (U.S. Patent # 5,326,211).

The teachings of Martin et al in view of Misciagno et al as they apply to claim 1 have been discussed previously. Though Martin et al teaches an isolation shutter in the form of an air lock means that opens and closes, it does not teach that the shutter slidably opens and closes.

Critchley teaches an air lock system for transferring objects into a containment or contained environment and the air lock system comprises doors that slidably open and close (Abstract, Column 1 Lines 4-8), thus making the air lock slidably open and close. Critchley is analogous to Martin et al in that it teaches a system or means that allow for the entry of objects



into a contained environment without letting the atmosphere within the contained environment escape.

At the time the present invention was made it would have been obvious to one of ordinary skill in the art to have an isolation shutter or air lock means that slidably opens and closes. Since Martin et al teaches that the shutter is a air lock means it would have been obvious to one of ordinary skill in the art to have that air lock means slidably open and close like the air lock means of Critchley since the air lock means configuration of Critchley allows for the entry of objects into a containment environment without letting atmosphere from that containment environment to escape.

### ***Conclusion***

Claims 1 through 9 and 21 have been rejected. No claims have been allowed. Claims 10 through 20 have been canceled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Wiczorek whose telephone number is (571)270-5341. The examiner can normally be reached on Monday through Friday; 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Cleveland can be reached on (571)272-1418. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MPW/

/Michael Wieczorek/  
Examiner, Art Unit 1792

/Michael Cleveland/

Supervisory Patent Examiner, Art Unit 1792